

Guidance Agenda: New & Revised Draft Guidances CDER is Planning to Publish During Calendar Year 2014

(See the Good Guidance Practices (GGPs) regulation on this Web page or
21 CFR 10.115 for details about the Guidance Agenda.)

CATEGORY — Advertising

- Brief Summary and Adequate Information for Use: Disclosing Risk Information in Consumer-Directed Print Advertisements and Promotional Labeling for Prescription Drugs
- Considerations for Regulatory Submissions of Promotional Labeling and Advertising Materials including Submissions in Electronic Format
- Direct-to-Consumer Television Advertisements – FDAAA DTC Television Pre-review Program
- Internet/Social Media Platforms with Character Space Limitations: Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices
- Internet/Social Media Platforms: Correcting Independent-Third Party Misinformation About Prescription Drugs and Medical Devices
- Internet/Social Media Advertising and Promotional Labeling of Prescription Drugs and Medical Devices – Use of Links

CATEGORY — Animal Rule

- Product Development Under the Animal Rule

CATEGORY — Biopharmaceutics

- Bioavailability and Bioequivalence Studies Submitted in NDA's or INDs for Orally Administered Drug Products – General Considerations
- Dissolution Testing and Specifications Criteria for Immediate-Release Solid Oral Dosage Forms Containing Biopharmaceutical Classification System Class 1 and 3 Drugs

CATEGORY — Biosimilarity

- Biosimilars: Additional Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009
- Clinical Pharmacology Data to Support a Demonstration of Biosimilarity to a Reference Product
- Considerations in Demonstrating Interchangeability to a Reference Product
- Labeling for Biosimilar Biological Products
- Reference Product Exclusivity for Biological Products Filed Under Section 351(a) of the PHS Act

CATEGORY — Chemistry

- Allowable Excess Volume and Labeled Vial Fill Size
- Analytical Procedures and Methods Validation for Drugs and Biologics
- Appropriate Package Type Terms for Injection Drugs or Biological Products in Packaged in Multiple-Dose, Single-Dose, and Single-Patient-Use Containers
- Specified Biotechnology and Specified Synthetic Biological Products – Annual Report
- Comparability Protocols for Approved Drugs: Chemistry, Manufacturing, and Controls Information
- Evaluation of Near Infrared Spectroscopy (NIR) Methods
- Immunogenicity- Related Considerations for the Approval of Low Molecular Weight Heparin for NDAs and ANDAs
- Liposome Drug Products: CMC, Human Pharmacokinetic and Bioavailability; and Labeling Documentation

CATEGORY — Clinical/Antimicrobial

- Attachment to Guidance on Antiviral Product Development – Conducting and Submitting Virology Studies to the Agency: Guidance for Submitting HIV Resistance Data
- Hospital-Acquired Bacterial Pneumonia and Ventilator-Associated Bacterial Pneumonia: Developing Drugs for Treatment
- Uncomplicated Gonorrhea: Developing Drugs for Treatment

CATEGORY — Clinical/Medical

- Chronic Fatigue Syndrome/Myalgic Encephalomyelitis: Developing Drugs for Treatment
- Common Issues in Drug Development for Rare Diseases
- Developing Drug and Biological Products for Analgesic Indications
- Modifications and Revisions of Risk Evaluation and Mitigation Strategies (REMS)
- Pregnant Women in Clinical Trials – Scientific and Ethical Considerations
- Standards for Clinical Trial Imaging Endpoints
- Upper Facial Lines: Developing Botulinum Toxin Products

CATEGORY — Clinical Pharmacology

- Clinical Lactation Trials – Trial Design, Data Analysis and Recommendations for Labeling
- General Clinical Pharmacology Considerations for Pediatrics Studies for Drugs and Biological Products
- Pharmacokinetics During Pregnancy and the Postpartum Period – Trial Design, Data Analysis, and Impact on Dosing and Labeling

CATEGORY — Clinical/Statistical

- Multiple Endpoints in Clinical Trials

CATEGORY — Quality: Facility, Production and Process Control

- Contract Manufacturing Arrangements for Drugs: Quality Agreements
- GXP Consideration for Outsourced IT (Cloud Computing) Systems in Medical Product Manufacturing and Clinical Study Environments
- Interim Good Manufacturing Practice for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug and Cosmetic Act
- Quality Systems Approach to Pharmaceutical Current Good Manufacturing Practice
- Submission of Field Alert Reports and Biological Product Deviation Reports

CATEGORY — Drug Safety

- Best Practices in Developing Proprietary Names
- Content, Format and Submission of Adverse Event Reports by Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug and Cosmetic Act
- Over-the-Counter Pediatric Liquid Drug Products Containing Acetaminophen

CATEGORY — Electronic Submissions

- Providing Regulatory Submissions in Electronic Format – Submissions Under Section 745A of the Federal, Food, Drug and Cosmetic Act
- Providing Regulatory Submissions in Electronic Format – Manufacturing Establishment Information
- Providing Regulatory Submissions in Electronic Format – Postmarketing Safety Reports
- Providing Regulatory Submissions in Electronic Format – Standardized Study Data
- Study Data Technical Conformance Guide and Data Standards Catalog

CATEGORY — IND

- Adverse Events: Collection and Reporting for Secondary Endpoints

CATEGORY — Labeling

- Indications and Usage Section of Labeling for Human Prescription Drugs and Biological Products – Content and Format

- Labeling for Human Prescription Drug and Biological Products Approved Under Accelerated Approval
- Pediatric Information: Incorporating into Human Prescription Drug and Biological Products Labeling
- Pregnancy, Lactation, and Females and Males of Reproductive Potential: Labeling for Human Prescription Drug and Biological Products – Content and Format Requirements
- Product Title and Initial U.S. Approval in the Highlights of Prescribing Information for Human Prescription Drug and Biological Products – Content and Format

CATEGORY — Procedural

- Applying the Criteria for Requiring a Risk Evaluation and Mitigation Strategy (REMS)
- Critical Path Innovation Meeting
- Division of Good Clinical Practice Compliance (DGCPC) Requested Contents for New Drug and Biologic Applications to Facilitate BIMO Inspection Planning and Conduct
- Drug Supply Chain Security Act (DSCSA) Implementation: Identification of Suspect Product and Termination of Notifications of Illegitimate Product for Finished Human Prescription Drugs
- DSCSA Implementation: Standards for the Interoperable Exchange of Information for Tracing of Finished Pharmaceuticals Drugs
- Integrated Summary of Safety
- Investigational New Drug Applications Prepared and Submitted by Clinical Sponsor Investigators
- National Drug Code (NDC) Assignment of CDER-Regulated Products
- Public Disclosure of FDA-Sponsored Studies
- Reporting Drug Sample Distribution Under Section 6004 of the Affordable Care Act
- Reporting Licensure by Wholesale Drug Distributor and Third-Party Logistic Providers
- Submission of Study Protocols for Drug Products with Certain Risk Evaluation and Mitigation Strategies for Review by the Office of Generic Drugs
- Survey Methodologies to Assess Risk Evaluation and Mitigation Strategies (REMS) Goal Related to Knowledge
- Use of a Master File for Shared System Risk Evaluation and Mitigation Strategies
- User Fees for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal, Food, Drug and Cosmetic Act

Note: Agenda items reflect guidances under development as of the date of this posting.